STUDY TITLE:

ISO INTRACUTANEOUS STUDY

EXTRACT

TEST ARTICLE:

Silver Coated Wound Dressing

IDENTIFICATION NO.

Code: cti 906 - 93 - 1

TEST FACILITY:

NAMSA
6750 Wales Road
Northwood, OH 43619

SPONSOR:

Howard Lo
Taiwan Textile Research Institute
Department of Textile Technology and Product Development
No. 6, Chen-Tian Road Taipei
Hsien R.O.C., 236
Taiwan

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

TABLE OF CONTENTS

	Page Number
SUMMARY	3
INTRODUCTION	4
MATERIALS	4
METHODS	5
RESULTS	7
CONCLUSION	7
RECORD STORAGE	7
APPENDIX 1 - ISO INTRACUTANEOUS OBSERVATIONS	8
CERTIFICATE OF QUALITY ASSURANCE INSPECTIONS	9

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

NAMSA

PEOPLE › SCIENCE › SOLUTIONS

LAB REPORT

SUMMARY

The test article, Silver Coated Wound Dressing, Code: cti 906 - 93 - 1, was extracted in 0.9% sodium chloride USP solution and sesame oil, NF. These extracts were evaluated for intracutaneous reactivity based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization.

A 0.2 ml dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of each rabbit. Similarly, the corresponding reagent control was injected on the left side of the back of each rabbit. The injection sites were observed immediately after injection. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection.

Under the conditions of this study, there was no evidence of irritation from the extracts injected intracutaneously into rabbits. The Primary Irritation Index Characterization for the extracts was negligible.

Study and Supervisory Personnel:

Brian T. Dougan
Marisa Delancey, AA, ALAT
Sara S. Hartman, ALAT
Colleen Stevenson, AA
Kathrina C. Ratliff, BS
Deedee M. Davis, BA
Darcy A. Pennington, BA

Approved by:

Joshua D. Moninger, B.S.
Study Director

October 6, 2004
Date Completed

/dt

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

INTRODUCTION

The test article identified below was extracted and the extracts were evaluated for biocompatibility based on the requirements of the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization. The purpose of the study was to determine whether leachables extracted from the material would cause local dermal irritant effects following injection into rabbit skin. The test article was received on August 30, 2004. The animals were injected on September 22, 2004, and the observations were concluded on September 25, 2004.

The study initiated by protocol signature on September 2, 2004, was conducted in accordance with the provisions of the FDA Good Laboratory Practice (GLP) Regulations, 21 CFR 58. A Certificate of Quality Assurance Inspections was issued with this report.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	Silver Coated Wound Dressing
Identification No.:	Code: cti 906 - 93 - 1
Stability Testing:	In progress (per sponsor)
Expiration Date:	Stable for duration of intended testing (per sponsor)
Storage Conditions:	Room Temperature
Vehicles:	0.9% sodium chloride USP solution (SC) sesame oil, NF (SO)
Preparation:	The sample was prepared aseptically. Based on a USP ratio of 120 cm^2:20 ml, a 60.0 cm^2 portion of the test article was covered with 10 ml of the vehicle. The test article was extracted and agitated in SC and SO at 37°C for 72 hours. The extraction vehicles without test article were similarly prepared to serve as reagent controls.

Condition of Extracts:

	Test	Control
SC:	clear with particulates	clear
SO:	slightly cloudy with particles and particulates*	clear

*The particles and particulates were allowed to settle and an aliquot for testing was drawn off the top.

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

METHODS

Test System:

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Female
Body Weight Range:	2.1 kg to 2.4 kg at selection
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Two
Identification Method:	Ear tag

Justification of Test System:

The intracutaneous injection test in rabbits is specified in the current ISO testing standards and has been used historically to evaluate biomaterial extracts.

Duplication of Experimental Work:

By signature on the protocol, the sponsor confirmed that the conduct of this study did not unnecessarily duplicate previous experiments.

Animal Management:

Husbandry:	Conditions conformed to Standard Operating Procedures which are based on the "Guide for the Care and Use of Laboratory Animals."
Food:	PROLAB® High Fiber Rabbit Diet was provided daily.
Water:	Provided *ad libitum* and delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test.
Housing:	Animals were individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environmental:	The room temperature was monitored daily. The temperature range for the room was within a range of 61-72°F. The room humidity was monitored daily. The humidity range for the room was 30-70%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Facility:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved were appropriately qualified and trained.

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

Selection: Only healthy, thin-skinned animals free of mechanical irritation or trauma that could interfere with the test were selected. To reduce the number of animals used for testing, and to comply with the directives of the NAMSA IACUC, rabbits on this study were used previously in an unrelated test model. Any previously evaluated test or control articles did not cause a response in the animals. Complete history of animal usage is traceable in laboratory records. Animals used for previous evaluations are identified in the report.

Experimental Procedure:

Within a 4 to 18 hour period before treatment, each rabbit was clipped free of fur from the back and both sides of the spinal column to yield a sufficient injection area. The clipped area of the back was wiped with a 70% alcohol soaked gauze pad just before injection and allowed to dry. Two rabbits were prepared per pair of extracts. A 0.2 ml dose of test article extract was injected intracutaneously into five separate sites on the right side of the back of each rabbit; 0.2 ml of the reagent control was injected into five separate sites on the corresponding left side of the back. Injections were spaced approximately 2 cm apart. The appearance of each injection site was noted immediately after injection. The animals were returned to their respective cages following the procedure.

Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection. Reactions were scored on a 0 to 4 basis. Any reaction at the injection sites was also noted. The reactions were evaluated according to the following subjective rating scale:

ERYTHEMA (ER)		EDEMA (ED)	
0	No erythema	0	No edema
1	Very slight erythema (barely perceptible)	1	Very slight edema (barely perceptible)
2	Well-defined erythema	2	Well-defined edema (edges of area well-defined by definite raising)
3	Moderate erythema	3	Moderate edema (raised approximately 1 mm)
4	Severe erythema (beet redness) to eschar formation preventing grading of erythema	4	Severe edema (raised more than 1 mm, and extending beyond exposure area)

For each animal, the erythema and edema scores obtained at each time interval were added together and divided by the total number of observations. This calculation was conducted separately for each test extract and reagent control. The score for the reagent control was subtracted from the score for the test extract to obtain the Primary Irritation Score. The Primary Irritation Score of each animal was added together and divided by the total number of animals to obtain the Primary Irritation Index (PII). The Primary Irritation Index was characterized by number and description as follows: 0-0.4 (negligible), 0.5-1.9 (slight), 2.0-4.9 (moderate), 5.0-8.0 (severe). Any adverse reaction noted in the test extract was compared to the corresponding reagent control.

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

RESULTS

All animals appeared clinically normal throughout the study. Results of scores for individual rabbits appear in Appendix 1. All injection sites appeared normal immediately following injection. The Primary Irritation Index (PII) and Characterization for each extract are summarized below:

Extract	Animal Number	Test Score Average	Control Score Average	Primary Irritation Score	Primary Irritation Score Total	Primary Irritation Index Characterization
SC	40788	0.0	0.0	0.0	0.0	Negligible
	40792	0.0	0.0	0.0		
SO	40788	0.0	0.0	0.0	0.0	Negligible
	40792	0.0	0.0	0.0		

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

CONCLUSION

Under the conditions of this study, there was no evidence of irritation from the extracts injected intracutaneously into rabbits. The Primary Irritation Index Characterization for the extracts was negligible.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files for a period of 5 years.

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

APPENDIX 1

ISO INTRACUTANEOUS OBSERVATIONS

Rabbit Number/ Gender	Body Weight (kg)	Extract	Scoring Interval											
			24 Hours				48 Hours				72 Hours			
			Test		Control		Test		Control		Test		Control	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
40788* Female	2.1	SC	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
40792* Female	2.4	SC	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
40788* Female	2.1	SO	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
40792* Female	2.4	SO	0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0
			0	0	0	0	0	0	0	0	0	0	0	0

*Previous use history traceable in laboratory records.

ER = Erythema
ED = Edema

SC = 0.9% sodium chloride USP solution
SO = sesame oil, NF

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

CERTIFICATE OF QUALITY ASSURANCE INSPECTIONS

Phase Inspected	Date	Auditor	Reports to Management and Study Director(s)	Date
Scoring	Sept. 23, 2004	K. J. Evener	Periodic Status Report	Oct. 4, 2004
Final Report Review	Oct. 6, 2004	C. E. Chmura		

This study will be included in the next periodic status report as completed.

Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. This study has been reviewed in accordance with the provisions of the FDA Good Laboratory Practice Regulations (21 CFR, Part 58).

QA Representative: Claire Chmura Oct 6, 2004

Claire E. Chmura, BS
Auditor, Quality Assurance

Date

/mel

NAMSA

Authorization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.

NAMSA

People > Science > Solutions

04T_50509
21778_001 21778

GLP SAMPLE SUBMISSION FORM

Sponsor (final report will be addressed and mailed to):

Company Name: ~~China Textile Institute~~ Taiwan Textile Research Institute
Address 1: Department of Textile Technology and Product Development No. 6, Chen-Tian Road Taipei
Address 2:
City, State, Zip: Hsien R.O.C.
Country: Taiwan
Attn: Howard Lo
Phone: 011-886-222-670321
Fax: 011-886-222-674163
e-mail address: citi917@cti.org.tw

Invoice Information:

Purchase Order Number:
Cost Estimate & Proposal No.: C04_1874
Credit Card # Mastercard/Visa
Card Holder Name:
Expiration Date:
Billing address:

Test Article Name (use EXACT wording as desired on final report)*: Silver Coated Wound Dressing

Identification Number Batch/Code/Lot (circle one): cti906-93-1

Storage Conditions: ☑Room Temperature; ☐Refrigeration; ☐Freezer; ☐Other _____ **Quantity Submitted:** _____

Physical description of test article (chemical/material type/color): water-insoluble, silver coated non-woven

Mixtures of test or control articles with carriers require analysis to demonstrate proper concentration, homogeneity and stability.
☐Sponsor will provide analytical methods; OR ☐Sponsor will perform analysis on representative aliquots provided by NAMSA.

Special Instructions:

***A detailed composition list and MSDS sheet must accompany any chemical or biologic test article. A certificate of testing or reprocessing must be submitted for any human tissue derived sample or clinically used medical device.**

Stability Data: The sponsor assures the above test article has been characterized for identity, strength, purity, and composition as required by FDA Good Laboratory Practice Regulations of 21 CFR Part 58.105. Stability testing is the responsibility of the sponsor and is subject to FDA audit. Characterization and stability information are also required for control articles. Please check the statement(s) applicable to both the test and control articles.

Test Article (√)	Control Article (√)	
√		Stability testing is in progress; article is stable for duration of intended testing.
		Stability testing is complete and on file with sponsor. Expiration date (test): Expiration date (control):
		Marketed product stability characterized by its labeling.

Disposition of Test/Control Article: ☑Discard ☐Return (include courier account number) via UPS/Federal Express/Other _____

Raw Data and Report Storage: All data including raw data, protocols, copies of reports, specimen blocks and slides will be archived for 5 years from completion of the final report. After the 5 year period has expired, these items will be destroyed unless specific instruction to return them is provided to NAMSA.

Authorized By Sponsor: John Huang Date: 2004. 8. 13

NAMSA Study Director: John D Monjo Date: September 2, 2004

Phone Toll Free: 1.866.666.9455

C080204_062
US MAIL China Textile

T083004_024
UPS STERIGENICS

REV102203

TI251-800
R-11

NAMSA™ GLP PROTOCOL T251

ISO INTRACUTANEOUS STUDY

EXTRACT

Sponsor:

Howard Lo
China Textile Institute
Department of Textile Technology
and Product Development No. 6,
Chen-Tian Road Taipei
Hsien R.O.C., Taiwan

Test Facility:

North American Science Associates, Inc. (NAMSA)
6750 Wales Road
Northwood, OH 43619-1011

NAMSA Use Only
Lab No. 04T-50509
CEP No. C04 1874

Approvals:

Protocol Submitted By (NAMSA): Paul Rudko
Paul Rudko, M.B.A.
Staff Toxicologist

Date Issued: 4-30-04

Principal Investigator: John Huang
(Sponsor)

Date Approved: 2004.8.13

Study Director (NAMSA):

Date Initiated: ~~SEPTEMB~~ SEPTEMBER 2, 2004
written on 9-2-04

/sas

NAMSA
Ensuring Medical Device Safety and Compliance™

Corp. Hdqtrs: 2261 Tracy Road, Northwood, OH 43619-1397 / 419.666.9455 / Fax 419.666.2954
3400 Cobb International Blvd., Kennesaw, GA 30152-7601 / 770.427.3101 / Fax 770.426.5692
9 Morgan, Irvine, CA 92618-2078 / 949.951.3110 / Fax 949.951.3280
Affiliates: France • Germany • Israel • Taiwan • United Kingdom

Test System:

Species:	Rabbit (*Oryctolagus cuniculus*)
Strain:	New Zealand White
Source:	Single USDA licensed supplier
Sex:	No particular gender is prescribed in this test
Body Weight Range:	2.0 kg or greater at selection
Age:	Young adults
Acclimation Period:	Minimum 5 days
Number of Animals:	Two per pair of extracts
Identification Method:	Ear tag

Justification of Test System:

The intracutaneous injection test in rabbits is specified in the current ISO testing standards and has been used historically to evaluate biomaterial extracts.

Duplication of Experimental Work:

By signature on this protocol, the sponsor confirms that the conduct of this study does not unnecessarily duplicate previous experiments.

Animal Management:

Husbandry:	Conditions will conform to Standard Operating Procedures which are based on the "Guide for the Care and Use of Laboratory Animals."
Food:	A commercially available, pelleted, rabbit feed will be provided daily.
Water:	Freely available, municipal water will be delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies should not have the potential to influence the outcome of this test.
Housing:	Animals will be individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environmental:	The room temperature will be monitored daily. The recommended temperature range for the room is 61-72°F. The room humidity will be monitored daily. The humidity range for the room is 30-70%. The light cycle will be controlled using an automatic timer (12 hours light, 12 hours dark).
Facility:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare.
Personnel:	Associates involved will be appropriately qualified and trained.
Selection:	Only healthy, thin-skinned animals free of mechanical irritation or trauma that could interfere with the test will be selected. To reduce the number of animals used for testing, and to comply with the directives of the NAMSA Institutional Animal Care and Use Committee (IACUC), rabbits on this study may have been used previously in an unrelated

NAMSA
Ensuring Medical Device Safety and Compliance™
Corp. Hdqtrs: 2261 Tracy Road, Northwood, OH 43619-1397 / 419.666.9455 / Fax 419.666.2954
3400 Cobb International Blvd., Kennesaw, GA 30152-7601 / 770.427.3101 / Fax 770.426.5692
9 Morgan, Irvine, CA 92618-2078 / 949.951.3110 / Fax 949.951.3280
Affiliates: France • Germany • Israel • Taiwan • United Kingdom

Evaluations and Statistics:

No statistical analysis of the data will be performed. For each animal, the erythema and edema scores obtained at each time interval will be added together and divided by the total number of observations. This calculation will be conducted separately for each test extract and reagent control. The score for the reagent control will be subtracted from the score for the test extract to obtain the Primary Irritation Score. The Primary Irritation Score of each animal will be added together and divided by the total number of animals. The value obtained is the Primary Irritation Index (PII). The Primary Irritation Index is characterized by number and description as follows: 0-0.4 (negligible), 0.5-1.9 (slight), 2.0-4.9 (moderate), 5.0-8.0 (severe). If the response in the initial test is equivocal, additional testing may be necessary. Any adverse reaction noted in the test extract will be compared to the corresponding reagent control.

Report:

The final report will include a description of the methods employed, individual dermal scores for each test and control injection site, and the assessment of the results (Primary Irritation Scores and the Primary Irritation Index).

Quality Assurance:

Inspections will be conducted at intervals adequate to assure the integrity of the study in conformance with 21 CFR 58.35(b)(3). The final report will also be reviewed for conformance to Section 58.185, Subpart J, of the GLP Regulations. A Certificate of Quality Assurance Inspections will be provided with the final report.

Records:

Test article and reagent control preparation data, dates of relevant activities (such as the study initiation and completion), the appearance of each injection site immediately after injection, individual dermal scores at 24, 48, and 72 hours, the Primary Irritation Score, and the Primary Irritation Index will be recorded.

All raw data pertaining to this study and a copy of the final report will be retained in designated NAMSA archive files for a period of 5 years.

Proposed Dates:

The study dates will be finalized by the study director following receipt of the sponsor-approved protocol and appropriate material for the study. Initiation of the study will be the date on which the study director signs the GLP protocol. Projected dates for starting the study (first treatment) and for the completion of the study (final report release) will be provided to the sponsor (or representative of the sponsor) and added to the protocol.

References:

21 CFR 58 (GLP Regulations).

Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, National Academy of Sciences (Washington: National Academy Press, 1996).

International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization.

OLAW, Public Health Service Policy on Humane Care and Use of Laboratory Animals.

United States Code of Federal Regulation (CFR) 9: The Animal Welfare Act.

United States Pharmacopeia (USP), current edition.

NAMSA
Ensuring Medical Device Safety and Compliance™

Corp. Hdqtrs: 2261 Tracy Road, Northwood, OH 43619-1397 / 419.666.9455 / Fax 419.666.2954
3400 Cobb International Blvd., Kennesaw, GA 30152-7601 / 770.427.3101 / Fax 770.426.5692
9 Morgan, Irvine, CA 92618-2078 / 949.951.3110 / Fax 949.951.3280
Affiliates: France • Germany • Israel • Taiwan • United Kingdom

NAMSA

PEOPLE > SCIENCE > SOLUTIONS

USA Corporate Headquarters	California	Georgia	Ohio
6750 Wales Rd	9 Morgan	3400 Cobb International Blvd	6750 Wales Rd
Northwood, Ohio 43619	Irvine, California 92618	Kennesaw, Georgia 30152	Northwood, Ohio 43619
T 866.666.9455 (toll free)	T 949.951.3110	T 770.427.3101	T 419.666.9455
F 419.662.4386	F 949.951.3280	F 770.426.5692	F 419.666.2954

September 9, 2004

Howard Lo
Taiwan Textile Research Institute
Department of Textile Technology and Product Development
No. 6, Chen-Tian Road Taipei
Hsien R.O.C., 236 Taiwan

PROTOCOL AMENDMENT I

Test Article: Silver Coated Wound Dressing

Identification: Code: cti 906 - 93 - 1

NAMSA Submission ID.: 04T_50509

We have received appropriate test article and approved protocol(s) for the program to be conducted in accordance with the Good Laboratory Practice (GLP) Regulations on the material described above. Below is a projected schedule for the work to be performed.

NAMSA Code	NAMSA Lab Number	Study	Estimated Start Date:	Estimated Report Release Date:
V0015_110	04T_50509_01	Cytotoxicity Study Using the ISO Agarose Overlay Method	September 16, 2004	September 29, 2004
TI261_300	04T_50509_02	ISO Maximization Sensitization Study - Extract - 0.9% SC Extract	September 16, 2004	November 10, 2004
TI261_300	04T_50509_03	ISO Maximization Sensitization Study - Extract - SO Extract	September 16, 2004	November 10, 2004
TI251_800	04T_50509_04	ISO Intracutaneous Study - Extract - 0.9% SC Extract	September 16, 2004	October 6, 2004
TI251_800	04T_50509_05	ISO Intracutaneous Study - Extract - SO Extract	September 16, 2004	October 6, 2004
TU012_500	04T_50509_06	USP and ISO Systemic Toxicity Study - Extract - 0.9% SC Extract	September 16, 2004	October 6, 2004
TU012_500	04T_50509_07	USP and ISO Systemic Toxicity Study - Extract - SO Extract	September 16, 2004	October 6, 2004
TI249_804	04T_50509_08	ISO Subcutaneous Implantation Study - 4 Week	September 16, 2004	November 17, 2004

NAMSA Code	NAMSA Lab Number	Study	Estimated Start Date:	Estimated Report Release Date:
V0019_100	04T_50509_09	In Vitro Hemolysis Study (Modified ASTM Method) - 0.9% SC Extract	September 16, 2004	October 6, 2004
T0118_904/S	04T_50509_10	Rat Subchronic Toxicity Study Following Subcutaneous Implantation (4 Week)	September 16, 2004	January 12, 2005

Joshua D. Moninger, B.S.
Study Director

SEPTEMBER 10, 2004
Date

cc: QA (NAMSA)
GLP study file

NAMSA

USA Corporate Headquarters

6750 Wales Rd.
Northwood, Ohio 43619
t 866.666.9455 (toll free)
f 419.662.4386