Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number 1150728-10*
	ZIP PENCIL BIOCOMPATABILITY	**Revision: A**
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1. REFERENCES

1010053-10	Risk Management
1020001-10	Device Master Record, Electrodes, E-Z Clean
ISO 10993-1	Biological Evaluation of Medical Devices
ISO 10993-5	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity
ISO 10993-10	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

2. SCOPE

This protocol pertains to the Zip Pencil Catalog number 2525-10 and 2525-15. For these tests, the two catalog numbers are considered equivalent and either may be tested to represent the other.

3. PURPOSE

The purpose of this test protocol is to specify biocompatibility testing required on the Zip Pencil to show compliance with ISO 10993-01: 2009.

4. BACKGROUND

The Zip Pencil is a new design of smoke evacuation pencil for Megadyne and requires testing to show conformance to standards. This pencil has a new design for the hand held pencil that incorporates materials that have not been previously tested by Megadyne.

5. DEFINITIONS AND ACRONYMS

EO	Ethylene Oxide
DMR	Device master Record

6. APPARATUS

These tests will be conducted at an outside contract laboratory per approved laboratory procedures. The test apparatus will be defined by the laboratory and referenced in the test report.

7. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

The sample sizes for the tests are defined in standard procedures. The tests require a minimum of 120 cm^2 of surface area for each sample. Each unit of the Zip Pencil exceeds this surface area. The number of samples submitted is as follows:

EO Exposure	10 total for use in tests below
Cytotoxicity (MEM)	2
Sensitization	6
Irritation	2

8. PROCEDURE

8.1. MATERIALS - ISO 10993-01 requires that the biological evaluation assess the physical and chemical characteristics of materials, history of clinical use or human exposure, existing toxicology or other safety data and test procedures. For the materials used in the Zip Pencil, the material information is as follows:

ABS - Pencil Body: Acrylonitrile Butadiene Styrene plastic that is used in similar devices with similar applications that are sold by Megadyne. This is known to be a low risk material for this application. The pencil body is not intended for patient contact but is in close proximity to the patient and inadvertent contact may occur. Therefore, biocompatibility testing is required.

TPR - Pencil Body Overmold: Thermoplastic Rubber used for enhancing the grip of the device for the surgeon. This type of material is commonly used in medical devices to improve grip. The material in the Zip Pencil is colored green which has not been tested by Megadyne. The pencil body is not intended for patient contact but is in close proximity to the patient and inadvertent contact may occur. Therefore, biocompatibility testing is required.

Nylon 6,6 – Buttons: Common plastic that is used in similar devices with similar applications that are sold by Megadyne. This is known to be a low risk material for this application. The buttons form part of the pencil body. They are not intended for patient contact but are in close proximity to the patient and inadvertent contact may occur. Therefore, this part will be included in the biocompatibility testing.

PC – Nozzle: Polycarbonate chosen for its transparent appearance and high tensile strength. This material is used in a similar device with a similar application that is sold by Megadyne. This is known to be a low risk material for this application. The material in the Zip Pencil is colored purple which has not been tested by Megadyne. The nozzle is not intended for patient contact but is in close proximity to the patient and inadvertent contact may occur. Therefore, biocompatibility testing is required.

HDPE – Tube Connectors: High Density Polyethylene is a common plastic used in medical devices. Not previously used by Megadyne in this type of application. The connector that joins the tubing to the pencil body is not intended for patient contact but is in close proximity to the patient and inadvertent contact may occur. Therefore, biocompatibility is required.

EVA – Tubing: Ethylene-vinyl acetate tubing is chosen for its transparent appearance and flexibility. This material is used in a similar device with a similar application that is sold by Megadyne. The tubing is used for removal of smoke from the surgical site and will not transport substances to the patient. This is known to be a low risk material for this application. The tubing is not intended for patient contact but is in close proximity to the patient and inadvertent contact may occur. Therefore, biocompatibility is required. The tubing is 10 or 15 feet long depending on catalog number, however, for the biocompatibility testing an eight inch piece will be included in the test. If the tubing were to contact the patient it would be a short section that makes the contact.

Polyolefin Elastomer – Tubing: Alternate tubing material chosen for its transparent appearance and flexibility. This material is known to be used in medical devices for different applications than the Zip Pencil. The tubing is used for removal of smoke from the surgical site and will not transport substances to the patient. Not previously used by Megadyne in this type of application. The tubing is not intended for patient contact but is in close proximity to the patient and inadvertent contact may occur. Therefore, biocompatibility testing is required.

The tubing is 10 or 15 feet long depending on catalog number, however, for the biocompatibility testing an eight inch piece will be included in the test. If the tubing were to contact the patient it would be a short section that makes the contact.

Electrode – Megadyne electrode made from SS, PTFE, and Polyolefin. Electrodes used in the Zip Pencil have been marketed for medical use by Megadyne for over 25 years. Biocompatibility of these electrodes is documented in the electrode DMR 1020001-10. Since the electrode has been previously tested and it has a small surface area compared to the rest of the device, the electrode will be omitted from the test.

8.2. TEST DECISION PROCESS - Based on ISO 10993-01:2009 flowchart "Figure 1", Testing is required per the following flowchart path:

- "Is there either direct or indirect contact"? YES
- "Obtain device material identification and chemical characterization shall be considered"? YES
- "Is the material same as in commercially available device"? NO, there are colorants in the device that are not known by Megadyne to be the same as other commercially available devices.
- "Is there sufficient justification and/or clinically relevant data (chemical and biological) for a risk assessment"? NO
- "Perform further evaluation of device based on chemical nature of materials and type and duration of contact".
- "Selection of biological tests (Annex A)", see below.
- "Testing and/or justification for omitting suggested tests" NO

8.3. REQUIRED TESTS - Based on ISO 10993-01:2009 "Annex A" Biological evaluation Tests, the following tests will be performed. Note that the device is category "External Communicating Device", Contact type "Tissue/Bone/Dentin" and contact duration "A- Limited". The tests required are:

Cytotoxicity (MEM)

Sensitization (Guinea Pig Maximization)

Irritation (Intracutaneous Reactivity)

Note: for traceability, these tests are listed in product specification X1200022-10 rev 01, ID numbers PRS 1401, PRS 1402 and PRS 1403.

These tests will be performed on devices that have been gamma sterilized to a minimum of 50 kGy which will match the maximum dose of the finished device. The device will also be exposed to EO sterilization to match the Megadyne EO cycle. The device will not be validated for EO sterilization but exposure to EO shows that the EO process does not have detrimental effects on the device. The test devices will have the cable and printed circuit boards removed because these components have no opportunity to contact the patient.

9. ACCEPTANCE CRITERIA

Reports will be issued by the test laboratory. The acceptance criteria for each test will be determined from the applicable standard as follows:

Test	Acceptance Criteria
EO Exposure	Proof of Exposure per the Protocol
Cytotoxicity (MEM)	Per Requirements of ISO 10993 -5:2009
Sensitization	Per Requirements of ISO 10993-10:2010 and Industry/Laboratory Requirements
Irritation	Per Requirements of ISO 10993-10:2010 and Industry/Laboratory Requirements

10. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	13-153-02	Initial Release	2013 NOV 06