

# MI-Sorb™

# Clinical Experience

Patricia Coutts RN  
June 5, 2008



# MMP Inhibition Therapy

## Role for MMP inhibition therapy in the clinic

What types of wounds?

- venous stasis
- diabetic foot
- pressure
- pyoderma gangrenosum
- vasculitis
- arterial



# MI-Sorb™ Clinical Experience

## Clinical impressions of MI-Sorb



# MI-Sorb™ Clinical Study

## Overall Objective:

Demonstrate MI-Sorb™ safety and efficacy.

A 6 week, randomized, single centre, multi-site pilot study

- Conducted by Dr. R.G. Sibbald
- 32 patients, two treatment arms, four indication groups

Lead-in – 2 weeks with LBP

Treatment arm – MI-Sorb™ (4 weeks)

Control arm – LBP (4 weeks)

## Efficacy Measurements:

- Wound exudate MMP activity
- **Wound bed appearance**
- Wound size



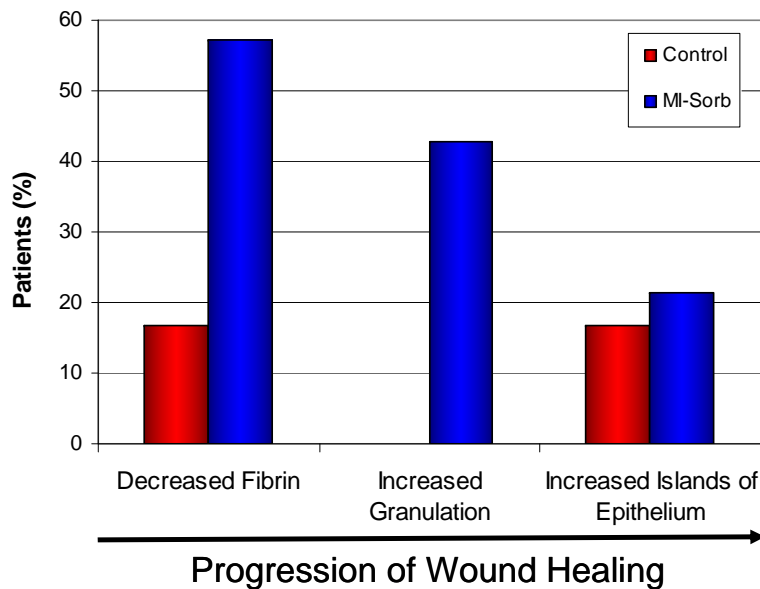
# MI-Sorb™ Clinical Study

## Clinical Trial – Patient Demographics

Patient Characteristic	Control Arm (n = 7)	MI-Sorb™ Treated Arm (n = 22)
<b>Mean Age</b> (range), years	61 (52-76)	60 (43-85)
<b>Gender</b> , Male/Female, %	71/29	68/32
<b>No. of Concomittant Medications</b> , mean	6	6
<b>No. of Concurrent Illnesses</b> , mean	3	3
<b>Mean Wound Size at Baseline</b> (range), cm <sup>2</sup>	8.7 (1.1-32.0)	6.9 (1.4-21.3)
<b>Mean Wound Age at Baseline</b> , months	21	21



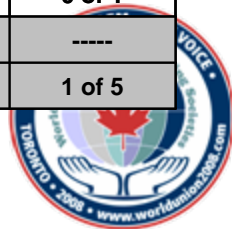
# Clinical Results - Wound Characteristics



MI-Sorb™ treated wounds progress towards healing

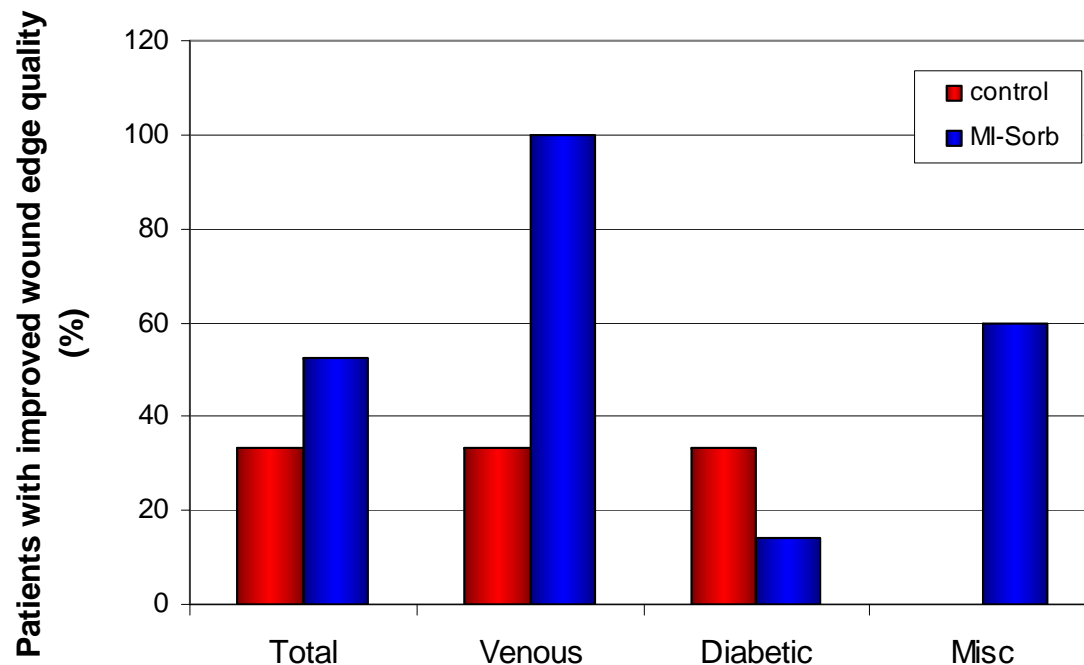
Diabetic and venous ulcers responded best to MI-Sorb™ treatment

Indication	Study Arm	Patients with Increased Islands of Epithelium	Patients with Increased Granulation	Patients with Decreased Fibrin
Diabetic Ulcer	Control	0 of 3	0 of 3	0 of 3
	Treatment	0 of 7	3 of 7	3 of 7
Venus Stasis Ulcer	Control	1 of 3	0 of 3	1 of 3
	Treatment	2 of 6	3 of 6	4 of 6
Pressure Ulcer	Control	-----	-----	-----
	Treatment	1 of 1	0 of 1	0 of 1
Misc. Ulcers	Control	-----	-----	-----
	Treatment	0 of 5	0 of 5	1 of 5



# Clinical Results - Wound Edge Quality

Wound edge quality was generally improved with MI-Sorb™ treatment



- Venous ulcers responded well
- Diabetic ulcers responded poorly

↓  
Mechanical  
irritation



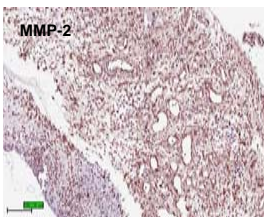
# Clinical Results – Wound Bed Histology

## Venous Ulcer Patients

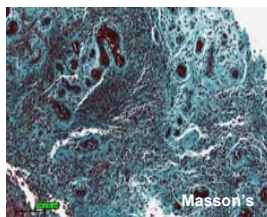
### Normalized MMP Activity Decreased 60.5%

*Case Study 1: A 54 year old male, presenting with a venous leg ulcer of 13 month duration; wound size at baseline 8.95 cm<sup>2</sup>*

#### Baseline

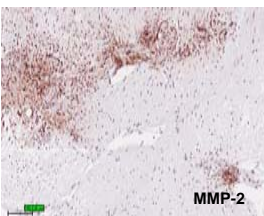


High levels of diffuse MMP-2 staining (brown)



Disorganized collagen structure (blue), presence of fibrin (red), highly cellular

#### After 4 weeks of MI-Sorb™ Treatment



Reduced MMP-2 staining (brown)

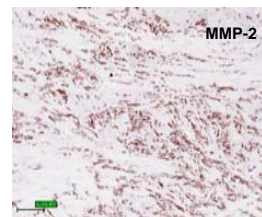


Organized collagen structure (blue), little fibrin (red), reduced cellularity

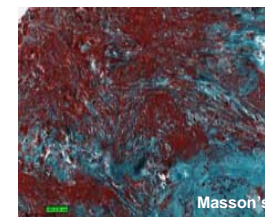
### Normalized MMP Activity Decreased 46.7%

*Case Study 2: A 50 year old female, presenting with a venous leg ulcer of 6 month duration, wound size at baseline 10.32 cm<sup>2</sup>*

#### Baseline

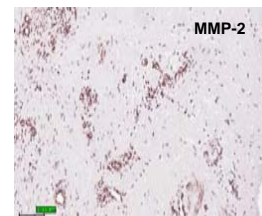


High levels of diffuse MMP-2 staining (brown)

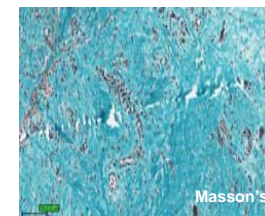


Disorganized collagen structure (blue), presence of fibrin (red), highly cellular

#### After 4 weeks of MI-Sorb™ Treatment



Reduced, focal MMP-2 staining (brown)



Disorganized collagen structure (blue), presence of fibrin (red), highly cellular

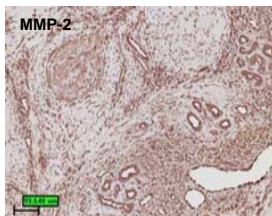
# Clinical Results – Wound Bed Histology

## Diabetic Ulcer Patients

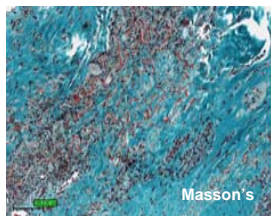
**Normalized MMP Activity Decreased 25.7%**

*Case Study 3: A 48 year old male, presenting with a diabetic foot ulcer of 17 month duration; wound size at baseline 6.64 cm<sup>2</sup>*

### Baseline

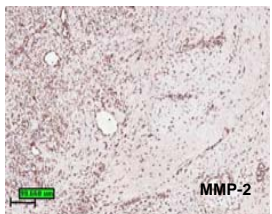


High levels of diffuse MMP-2 staining (brown)

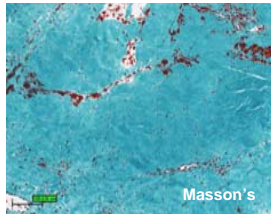


Disorganized collagen structure (blue), presence of fibrin (red), highly cellular

### After 4 weeks of MI-Sorb™ Treatment



Reduced MMP-2 staining (brown)

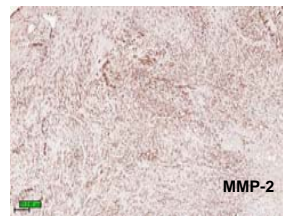


Organized collagen structure (blue), little fibrin (red), reduced cellularity

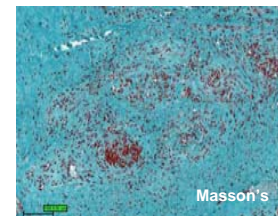
**Normalized MMP Activity Increased 76.9%**

*Case Study 4: A 59 year old female, presenting with a diabetic heel ulcer of 11 month duration; wound size at baseline 2.18 cm<sup>2</sup>*

### Baseline

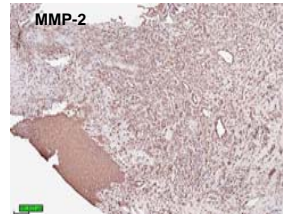


High levels of diffuse MMP-2 staining (brown)



Disorganized collagen structure (blue), presence of fibrin (red), highly cellular

### After 4 weeks of MI-Sorb™ Treatment



High levels of diffuse MMP-2 staining (brown)



Disorganized collagen structure (blue), presence of fibrin (red), highly cellular

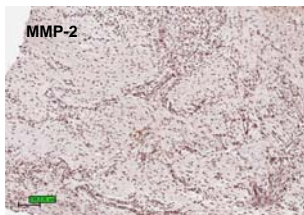
# Clinical Results – Wound Bed Histology

## Miscellaneous Ulcer Patient

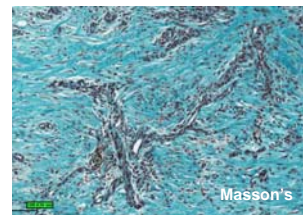
### Normalized MMP Activity Increased 6.6%

*Case Study 5: A 81 year old female, presenting with a miscellaneous leg ulcer of 16 month duration; wound size at baseline 21.3 cm<sup>2</sup>*

#### Baseline

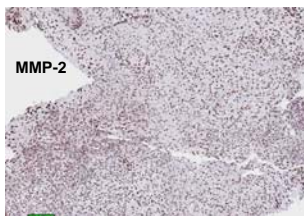


High levels of diffuse MMP-2 staining (brown)

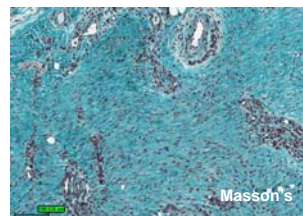


Disorganized collagen structure (blue), abundance of fibrin (red), highly cellular

#### After 4 weeks of MI-Sorb™ Treatment



High levels of diffuse MMP-2 staining (brown)



Disorganized collagen structure (blue), abundance of fibrin (red), highly cellular

# MI-Sorb™ Clinical Experience

## Case Study:

*A 43 year old male, paraplegic, presenting with a pressure sore on left hip of 24 month duration; wound area at baseline = 3.93 cm<sup>2</sup>*



**At Enrolment**

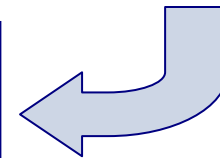


**After 2 weeks of  
MI-Sorb™ treatment**



**After 4 weeks of  
MI-Sorb™ treatment**

Reduction in normalized MMP activity: 35.5%  
Reduction in wound area: 22.4%  
Reduction in wound depth: 80%



# MI-Sorb™ Clinical Experience

## ■ Pros

- Absorbs exudate
- Ease of application
- Prevented maceration
- Easy to remove
- Patient comfort
- Another tool in the toolkit to provide best care

## ■ Cons

- Prototype small
- Needs moderate to high amount exudate
- Secondary dressing
- Not use where shearing forces may be a factor – eg. feet

Prototype has been modified from the lessons learned



# MI-Sorb™ Clinical Experience

## Summary

- ✓ Wounds of long standing
- ✓ Moderate to heavy exudate
- ✓ Easy to apply
- ✓ Effortless to remove
- ✓ Comfortable for patient
- ✓ Protects the peri - wound area
- ✓ Topography of wound needs to be considered
- ✓ Wounds progressed towards healing



# Thank You

For more information on MI-Sorb™ or  
copies of the presentations, please visit:

[www.rimontherapeutics.com](http://www.rimontherapeutics.com)

