APPENDIX A
What Did the Clinical Studies Show?

Burn Patients
IDRT has been evaluated in over 1,300 wound sites in 644 burn patients evaluated in a series of 4 studies. In a multicenter clinical trial, 149 patients were evaluated for safety and 106 patients (with 176 comparative wound sites) were included in an assessment of efficacy (how well it works). The area of wound site that supported the new skin graft is called “take.” Take was derived from the adverse event data and was calculated as: take (%) = [size of wound site (as a function of 100)] / (size of wound site (as a function of 100) + size of wound site (as a function of 100) * 100%)

The mean (average) effectiveness variable (characteristic) studied. IDRT had successful take (take >80%) in 66% of the wound sites (54 of 156). For this group of wound sites with successful take, the mean take was 81%, and the median take (middle value in a set of measurements) was 90%. IDRT failed to take (take <80%) in 31% of the wound sites (49 of 156 comparative wound sites). For this group, the mean take was 1.7% and the median take was 0%

Postapproval Study in Burns
A postapproval study of IDRT evaluated the safety and effectiveness in 216 patients, 841 wound sites. Effectiveness was measured by graft take. Overall mean average percent take for IDRT was 76.2% and the median percent take for IDRT was 96%. The mean (average) take of epithelial autograft was 86.3% with median take of 95%. The rate of effectiveness variable (characteristic) studied. IDRT had the effectiveness variable (characteristic) studied. IDRT had

APPENDIX B
Adverse events reported in the previous studies are as follows:

<table>
<thead>
<tr>
<th>Coded Symptom</th>
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<th>Heart Arrest</th>
<th>Kidney Failure</th>
<th>Epidermal autograft loss &gt;15%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psoriasis</td>
<td>10/126 (8.0%)</td>
<td>5/126 (4.0%)</td>
<td>6/126 (4.7%)</td>
<td>5/126 (4.0%)</td>
<td>1/126 (0.8%)</td>
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<td>Diabetes</td>
<td>5/126 (4.0%)</td>
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<td>3/126 (2.4%)</td>
<td>2/126 (1.6%)</td>
</tr>
<tr>
<td>Heart Arrest</td>
<td>6/126 (4.8%)</td>
<td>5/126 (4.0%)</td>
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<tr>
<td>Kidney Failure</td>
<td>15/126 (12.0%)</td>
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APPENDIX C
Incidence of adverse events occurring in >1% of the safety population in the Postapproval Study are as follows:

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There were no infections reported in the retrospective surgery study and the reported infection rate was 5% in the retrospective contracture reconstruction survey. No deaths were reported.
What Is IDRT Made of?

IDRT has two layers:

1. A thick underlayer made of pure collagen (protein) from shark cartilage.
2. A thin outer layer made of silicone.

What Can Patients Benefit from IDRT?

- Any patient with severe burns where it is desirable to minimize donor site wounds (using the patient’s own skin to apply to wounds)
- Any patient undergoing repair of scar contractures where it is desirable to minimize donor site wounds or if they have failed other treatments

Who CANNOT use IDRT?

- Use of IDRT is contraindicated in patients with a known hypersensitivity (allergy) to bovine collagen, chondroitin or silicone materials
- IDRT should not be used in the presence of infection

NOTE: There have been no clinical studies evaluating the use of IDRT in pregnant women.

What Other Choices or Treatments are Available?

The other choices for treatment are autologous (made from the patient’s skin) skin flaps and/or full- or split-thickness skin grafts. A skin graft or split-thickness autograft requires taking skin from an unaffected area of the patient's epidermis is applied to the wound area. IDRT helps repair the damaged tissue. When placed on a wound where the burned or scarred skin has been removed, IDRT provides scaffolding (support framework) for the blood vessels and other cells to regrow a new layer of dermis, while the collagen is absorbed into the body.

The silicone layer helps close the wound and prevent fluid loss. In approximately 14 to 21 days, the silicone layer can be removed and an ultra-thin graft of only the patient’s epidermis is applied to the wound area. IDRT immediately closes the burn wound and or eliminates the need for deep donor site wounds.

A benefit of IDRT is that it does not require the use of a full-thickness autograft to cover the new dermis. This thin graft allows for a minimal donor site wound that heals faster.

The long-term benefit of IDRT is the regeneration of the dermal tissue.

How is IDRT Used?

- Patients With Acute Burns
  When a patient is burned, their skin becomes so damaged that it must be removed surgically to prevent infection. After the surgeon removes the damaged skin, IDRT is used as a graft and shaped to the exact size and shape of the skin area it is to replace. IDRT is surgically secured with surgical sutures or staples. The IDRT areas are then covered with bandages. There are usually two layers of protective bandages.

- Patients Who Have Scar Contractures
  In patients with severe scar contractures, the exact same procedure is used. The only difference is the surgeon is removing scar tissue.

What Can I Do to Help My Burn or Wound to Heal?

- It is essential that you follow all of your healthcare provider’s instructions. You need to attend your scheduled appointments so that your healthcare provider can check your progress and assess your treated area.

- Postoperative Care
  The physician and nurses will monitor and treat all your IDRT sites while you are in the hospital.

- Home Care
  When you are home, you will not be changing your bandages. You will either be returning to the hospital clinic or a home health nurse will visit you. Be prepared to make frequent visits to the hospital because proper wound care is very important to successful grafting. You should be aware of any signs of infection, which can occur. Call your physician immediately if you notice any signs of infection. Signs of infection include a fever and swelling, odor, discharge, or pain in the IDRT site.

- If you are home, you MUST keep the IDRT sites completely dry. This is an important warning. It might be impossible to take a bath, shower or swim without getting the wound wet. Please consult your doctor about how to bathe during this time or about any other problems you may have.

Background

Human skin consists of two layers: the thin, outer layer called the epidermis and the much thicker underlayer called the dermis. When damaged, the epidermis is capable of healing itself. When there is complete loss of the dermis, it heals by scar formation rather than by regeneration (connective tissue repair). Severe burns involve the loss of both epidermis and dermis.

The treatment of severe burns usually requires skin grafting. This involves taking skin with both epidermis and dermis from unburned sites on the patient’s body (donor site) and grafting the donor site skin onto the burn wound. Patients who suffer severe burns often do not have sufficient donor site skin to immediately cover the burn wound.

The treatment of scar contractures involves surgically removing the scar (excising the scar) and applying a graft to the excised wound site to cover the wound. Again, a donor site is required and a second wound site is created at the skin graft donor site.

What is IDRT Made of?

IDRT has two layers:

1. A thick underlayer made of pure collagen (protein) from cows and a substance called glycosaminoglycan made from shark cartilage. Collagen and glycosaminoglycan are natural components of our skin.
2. A thin outer layer made of silicone.