bellafill®

Skin Test Instructions for Use

DESCRIPTION

Bellafill® Skin Test is an aseptically produced device composed of purified collagen gel. Each Bellafill® Skin Test consists of 3.5% bovine collagen, 2.7% phosphate buffer, 0.9% sodium chloride, 0.3% lidocaine hydrochloride, and 92.6% water for injection.

INDICATIONS

Bellafill® Skin Test is intended to be administered intradermally into the volar forearm to identify individuals who might show hypersensitivity to injectable bovine dermal collagen devices. Patients so identified are ineligible for treatment with Bellafill®.

CONTRAINDICATIONS

Bellafill® Skin Test contains bovine collagen and is contraindicated for patients with a history of allergies to any bovine collagen products, including but not limited to collagen injectables (except to verify questionable allergy), collagen implants, hemostatic sponges, and collagen-based sutures, because these patients are likely to have hypersensitivity to the Bellafill® Skin Test.

Bellafill® Skin Test is contraindicated for patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.

Bellafill® Skin Test contains lidocaine and is contraindicated for patients with known hypersensitivity to lidocaine.

Bellafill® Skin Test is contraindicated for patients undergoing or planning to undergo desensitization injections to meat products, as these injections can contain bovine collagen.

WARNINGS

If the Skin Test response is positive, the patient must not be treated with Bellafill®. If the Skin Test response is equivocal, it is recommended that a second Skin Test be administered in the opposite arm and evaluated prior to the initiation of treatment.

Some physicians have reported the occurrence of connective-tissue diseases such as rheumatoid arthritis, systemic lupus erythematosus (SLE), polymyositis (PM), and dermatomyositis (DM) subsequent to collagen injections in patients with no previous history of those disorders. Also, an increased incidence of cell-mediated and humoral immunity to various collagens has been found in systemic connective-tissue diseases such as rheumatoid arthritis, juvenile rheumatoid arthritis, and progressive systemic sclerosis (scleroderma). Patients with these diseases may thus have an increased susceptibility to hypersensitivity responses and/or accelerated clearance of their implants when injected with bovine dermal collagen preparations. Therefore, caution should be used when treating these patients, including consideration for further skin testing.

Patients with a history of dietary beef allergy should be carefully examined before they are administered the Bellafill® Skin Test since it is possible that the collagen component of the beef may be causing the allergy. More than 1 skin test is highly recommended prior to treating these patients.

PRECAUTIONS

As with all transcutaneous procedures, Bellafill® Skin Test injection carries a risk of infection. The usual precautions associated with injectable materials should be followed.

Results of the Skin Test may be inaccurate if patients are on immunosuppressive therapy.

Bellafill® Skin Test should be used with caution in patients who are atopic or have a history of allergies. This class of patient has a greater potential of ultimately exhibiting an allergic reaction to bovine collagen than do other patients.

Use of Bellafill® Skin Test at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled.

ADVERSE EVENTS

Rare anaphylactoid responses have been reported with collagen implants, including acute episodes of hypotension, difficulty breathing, tightness in chest, and/or shortness of breath. On rare occasions, the hypersensitivity response has progressed to a cystic reaction which may drain purulent material.

DIRECTIONS FOR USE

Note: The Bellafill® Skin Test should be stored at standard refrigerator temperatures (2 – 8˚C). DO NOT FREEZE. Do not remove syringes from tray until ready for use.

Prior to being administered the Bellafill® Skin Test, the patient should be provided with a copy of the Bellafill® Skin Test Results Card. The patient should be fully apprised of the purpose of and evaluation criteria for the Skin Test.

After verifying that contraindications to the proposed Bellafill® treatment do not exist, a Bellafill® Skin Test is administered. At the time of the initial evaluation, a complete medical history should be obtained.

The Bellafill® Skin Test syringe must be brought to room temperature before injection.

After cleansing the site, 0.1 cc Bellafill® Skin Test should be implanted intradermally into a volar forearm surface. The results of the Skin Test must be carefully evaluated for a 4-week period prior to the initiation of treatment with Bellafill®. Patients should be instructed to notify their physicians of any untoward test response observed within the 4-week period.

Discard the syringe after administration of the Bellafill® Skin Test.

a. **Positive Response**
   A positive response consists of erythema of any degree, induration, tenderness, and swelling, with or without pruritus, which can appear immediately following implantation and persists for more than 24 hours, or appears more than 24 hours following implantation.

b. **Equivocal Response**
   An equivocal response is one in which there is no localized skin reaction, but the patient does elicit a possible systemic reaction such as a rash, arthralgia (aching joints), or myalgia (aching muscles), which occurs at any time during the 4-week observation period. If an equivocal response is observed, a second injection in the opposite arm is required, with observation for an additional 4 weeks. Patients demonstrating a positive or equivocal response in this second test should not be treated.

TREATMENT WITH BELLAFILL® IS CONTRAINDICATED IN ANY PATIENT EXHIBITING A POSITIVE RESPONSE OR 2 EQUIVOCAL RESPONSES.

Clinical experience has shown that the importance of screening by means of the Bellafill® Skin Test cannot be overemphasized. However, a negative Skin Test does not preclude the possibility of the patient subsequently developing a delayed hypersensitivity response to the implant material following treatment exposure.

HOW SUPPLIED

Bellafill® Skin Test is an aseptic product packaged in configurations of 2 or 5 syringes in one sealed tray per box. Each syringe contains 0.3cc of purified collagen gel.

Each Bellafill® Skin Test consists of 3.5% bovine collagen, 2.7% phosphate buffer, 0.9% sodium chloride, 0.3% lidocaine hydrochloride, and 92.6% water for injection. Bellafill® Skin Test syringes are appropriate only for testing prior to treatment with Bellafill®.

Each syringe is sealed for single-patient use. The tip of the syringe is sealed with a Winged cap. The tray lid is sealed with a cover. Do not use if package is damaged or the cover is broken or removed. Do not resterilize.

STORAGE DIRECTIONS

Bellafill® Skin Test syringes should be stored at standard refrigerator temperatures (2 – 8˚C). DO NOT FREEZE. Do not remove syringes from tray until ready for use.

Bellafill® Skin Test has a clear appearance. In the event that a syringe does not have a clear appearance, do not use the syringe, and notify Suneva Medical at 844-BELLAFILL (844-235-5234). Outside the United States, call ++1-858-550-9999.

To place an order, contact Suneva Medical, Inc. In the United States, call toll-free: 844-BELLAFILL (844-235-5234). Outside the United States, call ++1-858-550-9999. Orders may also be sent by fax to 858-550-9997, or email to orders@sunevamedical.com.

CAUTION: Federal law restricts this device to sale by or on the order of a physician or licensed practitioner.

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