

Preliminary screening form

(You can show your Ophthalmologist/low vision professional pages 1, 2 and 5 after you fill them for their initial evaluation).

Please check “Yes” or “No” for each question.

Stage 1:

If any of the answers are “No”, the patient may not participate.

	Yes	No
1. The patient suffers from bilateral macular degeneration.		
2. The patient is 60 years old or more.		
3. The patient has shown interest and understands the need for visual improvement.		
4. The patient has visual acuity between 20/80 and 20/800 (in the operated eye).		
5. The eye being considered for surgery shows an improvement in visual acuity when tested with an external telescope with x2.5 magnification.		
6. The patient has no ocular pathology or previous surgery in the operative eye except for cataract and age-related macular degeneration.		
7. The fellow eye has no ocular disease that may affect the peripheral visual field.		
8. The patient has the mental ability to undergo the testing required for the surgery and is likely to complete the entire course of follow-up.		
9. The patient agrees to sign a written informed consent.		

Answers to questions “1 through 9” must all be “Yes” for the patient to be a candidate for implantation.

Please check “Yes” and “No” for each question.

	Yes	No
10. The patient is currently involved, or in last 30 days, has been involved in any clinical trial of an investigational drug or device.		
11. The patient is immunosuppressed, uses systemic steroid or anticoagulants.		
12. The patient has known sensitivity to any of the medications that will be used after surgery.		
13. The patient has severe communication impairment or a severe neurological disorder, which would prevent or interfere with the requirements.		

Answers to questions “10 through 13” must all be “No” for the patient to be a candidate for further evaluation.

If the answers to questions, “1 through 9” are all “Yes” and the answers to questions “10 through 13” are all “No”, proceed to the next stage of testing.

Stage 2:

For stage 2 the patient uses a chart that can help to demonstrate some of the possible outcomes of OriLens implantation.

The test should be performed indoor with regular room light condition (the room should not be darkened).

The patient should be at distances of 30 cm, 1 meter and 2 meters from the screen.

If the patient uses glasses, s/he should wear them during the test.

Please look at the chart on the screen with the chart.

You will need to adjust the size of the chart, so that the letter H (on the top left side of the screen) would be roughly 6 cm high for testing your distance vision (1 meter and above). For near vision testing (less than 1 meter) you will need the same letter H to be 1.2 cm high.

You can adjust the size of the chart using the ↑↓ buttons on the right side of the chart.

You can also adjust the image contrast from high to low by choosing from the menu on the right side of the chart. Testing should be performed for both high contrast and low contrast charts.

For purposes of filling the data below correctly, line 1 is the largest line that starts with the letter H, line 2 is the second largest line that starts with the letter N, line 3 starts with C and so forth.

Begin with a distance of 1 meter from the screen.

Cover your left eye completely (while the right eye is being tested).

Read the smallest letters that you can detect on the chart (consider only lines that can be read completely – the entire 5 letters).

Count the number of lines on the chart that you can read. For example: if you can read the letters CZSHN, record in the table below the number 3 for 1 meter with your right eye, as this is the third line on the chart and you were tested for one meter with your right eye.

Then, cover your right eye and read the smallest letters and fill in the results for the left eye.

Now you can find out what will be the best possible result that you may reach following OriLens implantation.

The best possible result would be 3 lines smaller than the result that you reached in the initial self-testing. For example, if you could read line 4, which is ONVSR, then the best result that you may be able to achieve after implantation is line 7, which shows the letters DVOHC on the chart in front of you.

Another way to demonstrate what could be achieved is to look at a line that is 3 lines higher than what you read and note that the line that you could read (line 4 on that example) will be seen by your eye in the size of line 1 (which is 3 lines bigger).

You should perform the same test from a distance of two meters, only if you could detect all of the letters in the chart for a distance of one meter. If you could not read the entire chart from one meter, you do not to test yourself from two meters. Simply ignore the two meter test.

Please note that there is no guarantee that you will reach an improvement of 3 lines. There are several factors, such as your eye condition, the progression of the disease and the surgical procedure that may affect the benefit that you may achieve from the implantation.

Also, it is important to note that the actual image would be seen in lower contrast after implantation, which means the luminosity will be somehow darker.

In order to simulate the lower contrast that you will see with the implant, please click on the "low contrast" button near the chart and you will be able to see the same chart and compare the normal contrast and the low contrast that you will experience after surgery.

Then, record the smallest line that you can read in low contrast from one meter, and, if applicable, from two meters.

Now that you have completed testing your eye for distance vision, let's test you for near vision (reading).

Use your reading glasses for this test (if you do not have one that you use a +3.00 sph normal reading glasses).

Adjust the chart for near vision (as explained above). The test should be performed at a distance of 30 cm from the screen.

Follow the same instructions as for distance vision: cover one eye, test for the smallest line that you can see completely, and look for three lines below for a simulation on what can be achieved for near. You can also simulate the new contrast if you click on the "low contrast button".

Fill the data that you have recorded from the chart in the table below. The results that you have recorded in the table below may serve you when you visit your ophthalmologist for consultation.

Patient Initial Self-Testing before OriLens Implantation

Name & Surname: _____ Age: _____

Gender: _____ Country: _____

Past Treatments (if any): Laser/PDT, if yes, no. of injections performed: _____

Tel: _____ Mobile Tel: _____

e-mail: _____

Please write the smallest line that the patient could read in the chart.

Add LOGMAR values according to the following key:

Line 1 = LogMAR 1.0	Line 5 = LogMAR 0.6	Line 9 = LogMAR 0.2	Line 13 = LogMAR -0.2
Line 2 = LogMAR 0.9	Line 6 = LogMAR 0.5	Line 10 = LogMAR 0.1	Line 14 = LogMAR -0.3
Line 3 = LogMAR 0.8	Line 7 = LogMAR 0.4	Line 11 = LogMAR 0	
Line 4 = LogMAR 0.7	Line 8 = LogMAR 0.3	Line 12 = LogMAR -0.1	

Distance	Smallest line that patient could read – in high contrast conditions	LogMar (according to the table above)
30 cm		
1 meter		
2 meters		

Distance	Smallest line that patient could read – in low contrast conditions	LogMar (according to the table above)
30 cm		
1 meter		
2 meters		